IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.	:	10/648536 Confirmation No. 4649
Applicant	:	LOCKERBIE, Robert Owen
Filed	:	08/25/2003
Title:		Induction of and Maintenance of Nucleic Acid Damage in Pathogens Using Riboflavin And Light
TC/A.U.	:	1651
Examiner	:	LEE, Jae W.
Docket No.	:	B0175-US02
Customer No.:		24994

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APPEAL BRIEF UNDER 37 C.F.R 41.37

Pursuant to 37 C.F.R 41.37, Appellants submit this Appeal Brief to the Board of Patent Appeals and Interferences, for Applicant's appeal from the October 18, 2007 Final Office Action. In light of the Notice of Appeal filed on December 11, 2007, this Appeal Brief is being timely filed along with payment of the Appeal Brief fee as set forth in 37 C.F.R. 41.37(a)(1) and (2).

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I. Real Party in Interest

The real party in interest is Navigant Biotechnologies, LLC, the assignee of the entire right, title and interest in the application at issue.

II. Related Appeals and Interferences

There are currently no related appeals or interferences pending before the Board of Patent Appeals and Interferences.

III. Status of Claims

Claims 2,3, and 20 were cancelled. Claims 8, 11-19 were withdrawn. Claims 1, 4-7, 9, 10 and 21-23 stand rejected. Therefore, claims 1, 4-7, 9, 10 and 21-23 are the subject of this appeal.

The claims are set forth in the attached Appendix (pages14-16).

IV. Status of Amendments

Claims 2, 3, and 20 were cancelled and claims 1, 5, 10, and 21 were amended by Applicant in the Amendment and Response filed on August 6, 2007. The Examiner entered the claim amendments in the Final Office Action dated October 18, 2007.

V. Summary of Claimed Subject Matter

Independent claim 1 is directed toward a process for preventing self-repair of nucleic acid of pathogenic white blood cells, bacteria and/or viruses which may be contained in blood components. The steps of this process include: adding to the blood components a riboflavin photosensitizer (page 8, lines 10-18 and 20-24); irradiating the blood components and riboflavin with light in a visible or UV range at an appropriate wavelength to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria and/or viruses to cause permanent damage to the nucleic acid (page 8, lines 29-31; page 12, Example 3; page 13, see Examples 4 and 5); preventing self-repair of the nucleic acid (page 8, lines 1-5); and maintaining the permanent damage to the nucleic acid caused by the photosensitizer and light over time such that the pathogenic white blood cells, bacteria and/or viruses will not reproduce in the blood components (page 8, lines 1-5; page 9 see Example 1; Fig.4).

Dependent claim 4 is directed toward an optional step of adding a quencher to the fluid (page 9, lines 16-18).

Dependent claim 5 is directed toward a description of materials that can be used as quencher (page 9, lines 18-22).

Dependent claim 6 is directed toward an optional step of adding additives to the fluid (page 9, lines 25-28).

Dependent claim 7 is directed toward a blood component which comprises platelets (page 10, lines 9-18).

Dependent claim 9 is directed toward the UVB light used to irradiate the fluid and photosensitizer (page 13, see Example 5).

Dependent claim 10 is directed toward a process of adding riboflavin to the blood components at a final concentration of between about 50-500 μM. (page 8, lines 22-24).

Independent claim 21 is directed toward a process for providing pathogen reduced blood or blood components suitable for re-infusion into a patient. The steps of this process include: damaging the nucleic acid of any pathogenic white blood cells, bacteria or viruses which may be present with the blood or blood components (page 8, lines 1-7; lines 24-26; lines 29-33); adding riboflavin to the fluid containing blood or blood components and any pathogens (page 8, lines 20-24); and exposing the fluid to light to activate the riboflavin to maintain the nucleic acid damage of the pathogens (page 8, lines 29-31; page 13, see Example 4).

Dependent claim 22 is directed toward a step of exposing the fluid to light in the UVB range (page 13, see Example 5).

Dependent claim 23 is directed toward the riboflavin added to the fluid at a final concentration of between about 50-500 μM (page 8, lines 22-24).

VI. Grounds of Rejection To Be Reviewed on Appeal

A. Whether the rejection of claims 1, 4-7, 9, 10 and 21-23 under 35 USC 112, first paragraph, written description, as failing to comply with the written description requirement should be reversed.

B. Whether the rejection of claims 1, 4-7, 9, 10 and 21-23 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement should be reversed.

C. Whether the rejection of claims 1, 6, 7, 10, 21 and 23 under 35 USC 102(e) as being anticipated by Goodrich et al. (US Patent No. 6,258,577) should be reversed.

VII. Argument

A. The rejection of claims 1, 4-7, 9, 10 and 21-23 under 35 USC 112, first paragraph, written description, as failing to comply with the written description requirement should be reversed.

In the final office action, the Examiner argues that the phrase "blood components" in claim 1 and 21 is not defined in the specification. Applicants disagree, as the Examiner has not established a prima facie case as to why a person skilled in the art would not know what blood components are.

As set forth in MPEP 2163.04 (I), in rejecting a claim for lack of written description, the examiner must set forth express findings of fact which support the lack of written description conclusion. These findings should: (B) establish a prima facie case by providing reasons why a person skilled in the art at the time the application was filed would not have recognized that the inventor was in the possession of the invention as claimed in view of the disclosure of the application as filed."

"Blood component" is defined on page 1, line 9 of the specification, which states that "[W]hole blood collected from volunteer donors for transfusion into recipients is typically separated into its components: red blood cells, white blood cells, platelets, plasma and plasma proteins." One skilled in the art of pathogen reduction would know what constitutes "blood components" from this description.

The Examiner also argues that "the specification lacks adequate description of the genus of "riboflavin photosensitizers"". Riboflavin photosensitizer (7, 8-dimthyl-10-ribityl isoalloxazine) is not a genus, it is a species. The genus would be alloxazine (see page 6 of the specification), however, alloxazine is not claimed. Claim 1 recites a riboflavin photosensitizer. Riboflavin is one of several species falling under the alloxazine genus. This definition is found on page 6 of the specification.

As set forth in the Examiner guidelines at MPEP 2163 (II) (3) (i) "for each claim drawn to a single embodiment or species: A. determine whether the application describes an actual reduction to practice." The description on page 6 as well as the examples describes the actual reduction to practice using riboflavin as the photosensitizer.

B. The rejection of claims 1, 4-7, 9, 10 and 21-23 under 35 USC 112, first paragraph, as failing to comply with the enablement requirement should be reversed.

In the final office action, the Examiner stated that "the scope of the claim is not commensurate with the disclosure of the instant application because the claims rejected under this statute do not place any structural limits on the "riboflavin photosensitizers". The specification does not support the broad scope of the claims which encompass all modifications and fragments of any "riboflavin photosensitizer" that can be used in the claimed method, especially those modifications and fragments that do not produce reactive oxygen species upon irradiation with light."

Applicants disagree with this rejection as they are not claiming "any riboflavin photosensitizer" or "modifications and fragments [of riboflavin] that do not produce reactive oxygen species" as stated by the Examiner. Claim 1 of the present application claims only riboflavin photosensitizer, which, as stated above is defined on page 6 of the specification.

MPEP 2164.01 provides that any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims to enable one skilled in the art to make and use the claimed invention. The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde* 242 US 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention unreasonable?

As stated above, claim 1 of the present application is directed only to riboflavin, not to any modifications or fragments thereof. No undue experimentation to practice the claimed invention is required.

C. Whether the rejection of claims 1, 6, 7, 10, 21 and 23 under 35 USC 102(e) as being anticipated by Goodrich et al. (US Patent No. 6,258,577) should be reversed.

Applicant disagrees that the present invention is anticipated by the Goodrich reference. As set forth in MPEP 2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California* 814 F2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The Goodrich reference does not describe either expressly or inherently "irradiating the blood components and riboflavin with light in a visible or UV range at an appropriate wavelength to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria and/or viruses to cause permanent damage to the nucleic acid;

preventing self-repair of the nucleic acid; and

wherein the permanent damage to the nucleic acid caused by the photosensitizer and light is maintained over time such that the pathogenic white blood cells, bacteria and/or viruses will not reproduce in the blood components" as in claim 1 of the present application. There is also no description in Goodrich of "exposing the blood or blood components to UV or visible light to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria or viruses to prevent them from reproducing in the blood or blood component after re-infusion into the patient" as in claim 21 of the present invention.

The Goodrich reference does not expressly disclose the limitations in claims 1 and 21 that riboflavin and light fragment the nucleic acids of pathogens, preventing the pathogens from repairing themselves. There is no disclosure that this inability to self-repair prevents the pathogens from reproducing in the blood components.

Conclusion

For at least the reasons given above, the Board of Patent Appeals and Interferences should reverse the claim rejections under 35 USC 112, first paragraph and 35 USC §102(e) and permit allowance of claims 1, 4-7, 9, 10 and 21-23.

It is believed there is a fee of $510.00 due for the filing of a brief in support of an appeal. Please charge this fee and/or any other necessary fees to our Deposit Account 03-2316.

Respectfully submitted,

02-06-2008
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VIII. CLAIMS APPENDIX

Appealed claims:

1. (Currently amended) A process for preventing self-repair of nucleic acid of pathogenic white blood cells, bacteria and/or viruses which may be contained in blood components comprising the steps of:

adding to the blood components a riboflavin photosensitizer;

irradiating the blood components and riboflavin with light in a visible or UV range at an appropriate wavelength to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria and/or viruses to cause permanent damage to the nucleic acid;

preventing self-repair of the nucleic acid; and

wherein the permanent damage to the nucleic acid caused by the photosensitizer and light is maintained over time such that the pathogenic white blood cells, bacteria and/or viruses will not reproduce in the blood components.

2. (Cancelled)

3. (Cancelled)

4. (Original) The process of claim 1 further comprising adding a quencher to the fluid.

5. (Currently amended) The process of claim 4 wherein the quencher further comprises a quencher selected from the group consisting essentially of glutathione, n-acetyl-cysteine, cysteine, adenine, histidine, tyrosine, tryptophan, ascorbate, vitamin E, trolox, alpha-tocopheral polyethylene glycol succinate (TPGS) and mixtures thereof.

6. (Original) The process of claim 1 further comprising adding to the fluid a solution containing additives to enhance blood component viability.

7. (Original) The process of claim 1 wherein the blood component further comprises platelets.

8. (Withdrawn) The process of claim 1 wherein the blood component further comprises red blood cells.

9. (Original) The process of claim 1 wherein the light used to irradiate the fluid and photosensitizer is in the UVB range.

10. (Currently amended) The process of claim 1 wherein the riboflavin is added to the blood components at a final concentration of between about 50-500 μM.

11. (Withdrawn) A process for inactivating white blood cells which may be contained in a fluid comprising:

adding to the fluid containing white blood cells an effective amount of riboflavin;

exposing the fluid and riboflavin to light of an appropriate wavelength to activate the riboflavin and cause damage to the nucleic acid of the white blood cells; and

substantially maintaining the damage to the nucleic acids of the white blood cells to prevent re-activation of the white blood cells.

12. (Withdrawn) The process of claim 11 wherein the fluid further comprises red blood cells.

13. (Withdrawn) The process of claim 11 wherein the fluid further comprises platelets.

14. (Withdrawn) The process of claim 11 wherein the fluid further comprises plasma.

15. (Withdrawn) The process of claim 11 wherein the light to expose the fluid and riboflavin is in the UVB range.

16. (Withdrawn) The process of claim 11 wherein the riboflavin is added to the fluid at a final concentration of between about 50-500 μM.

17. (Withdrawn) A fluid suitable for transfusing into a patient comprising red blood cells treated by the process of claim 11.

18. (Withdrawn) A fluid suitable for transfusing into a patient comprising platelets treated by the process of claim 11.

19. (Withdrawn) A fluid suitable for transfusing into a patient comprising plasma treated by the process of claim 11.

20. (Cancelled)

21. (Currently amended) A process for providing pathogen reduced blood or blood components suitable for re-infusion into a patient comprising:

damaging the nucleic acid of any pathogenic white blood cells, bacteria or viruses which may be present with the blood or blood components;

adding riboflavin to the blood or blood components; and

exposing the blood or blood components to UV or visible light to activate the riboflavin to fragment the nucleic acid of the pathogenic white blood cells, bacteria or viruses to prevent them from reproducing in the blood or blood component after re-infusion into the patient.

22. (Original) The process of claim 21 wherein the step of exposing the fluid to light further comprises exposing the fluid to light in the UVB range.

23. (Original) The process of claim 21 wherein the riboflavin is added to the fluid at a final concentration of between about 50-500 μM.

IX. Evidence Appendix

None

X. Related Proceedings Appendix

None